

§ 422.9

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§ 422.9 Documents required.

(a) A research institution that conducts USDA-funded extramural research must maintain the following documents related to an allegation of research misconduct at the research institution:

(1) A written statement describing the original allegation;

(2) A copy of the formal notification presented to the subject of the allegation;

(3) A written report describing the inquiry stage and its outcome including copies of all supporting documentation;

(4) A description of the methods and procedures used to gather and evaluate information pertinent to the alleged misconduct during inquiry and investigation stages;

(5) A written report of the investigation, including the evidentiary record and supporting documentation;

(6) A written statement of the findings; and

(7) If applicable, a statement of recommended corrective actions, and any response to such a statement by the subject of the original allegation, and/or other interested parties, including any corrective action plan.

(b) The research institution must retain the documents specified in paragraph (a) of this section for at least 3 years following the final adjudication of the alleged research misconduct.

§ 422.10 Reporting to USDA.

Following completion of an investigation into allegations of research misconduct, the institution conducting extramural research must provide to the ARIO a copy of the evidentiary record, the report of the investigation, recommendations made to the institution's adjudicating official, the adjudicating official's determination, the institution's corrective action taken or planned, and the written response of the individual who is the subject of the allegation to any recommendations.

§ 422.11 Research records and evidence.

(a) A research institution that conducts extramural research supported by USDA funds, as the responsible legal entity for the USDA-supported research, has a continuing obligation

to create and maintain adequate records (including documents and other evidentiary matter) as may be required by any subsequent inquiry, investigation, finding, adjudication, or other proceeding.

(b) Whenever an investigation is initiated, the research institution must promptly take all reasonable and practical steps to obtain custody of all relevant research records and evidence as may be necessary to conduct the research misconduct proceedings. This must be accomplished before the research institution notifies the researcher/respondent of the allegation, or immediately thereafter.

(c) The original research records and evidence taken into custody by the research institution shall be inventoried and stored in a secure place and manner. Research records involving raw data shall include the devices or instruments on which they reside. However, if deemed appropriate by the research institution or investigator, research data or records that reside on or in instruments or devices may be copied and removed from those instruments or devices as long as the copies are complete, accurate, and have substantially equivalent evidentiary value as the data or records have when the data or records reside on the instruments or devices. Such copies of data or records shall be made by a disinterested, qualified technician and not by the subject of the original allegation or other interested parties. When the relevant data or records have been removed from the devices or instruments, the instruments or devices need not be maintained as evidence.

§ 422.12 Remedies for noncompliance.

USDA agencies' implementation procedures identify the administrative actions available to remedy a finding of research misconduct. Such actions may include the recovery of funds, correction of the research record, debarment of the researcher(s) that engaged in the research misconduct, proper attribution, or any other action deemed appropriate to remedy the instance(s) of research misconduct. The agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct

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was knowingly conducted, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare. In determining the appropriate administrative action, the appropriate agency must impose a remedy that is commensurate with the infraction as described in the finding of research misconduct.

§ 422.13 Appeals.

(a) If USDA relied on an institution to conduct an inquiry, investigation, and adjudication, the alleged person(s) should first follow the institution's appeal policy and procedures.

(b) USDA agencies' implementation procedures identify the appeal process when a finding of research misconduct is elevated to the agency.

§ 422.14 Relationship to other requirements.

Some of the research covered by this part also may be subject to regulations

of other governmental agencies (*e.g.*, a university that receives funding from a USDA agency and also under a grant from another Federal agency). If more than one agency of the Federal Government has jurisdiction, USDA will cooperate with the other agency(ies) in designating a lead agency. When USDA is not the lead agency, it will rely on the lead agency following its policies and procedures in determining whether there is a finding of research misconduct. Further, USDA may, in consultation with the lead agency, take action to protect the health and safety of the public, to promote the integrity of the USDA-supported research and research process, or to conserve public funds. When appropriate, USDA will seek to resolve allegations jointly with the other agency or agencies.

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